

EPA Registration # 70552-2

Material Sent for Data Extraction

Reg. # 70SS2-2

Description: He too technical

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated MAR 2 6 2012

☐ Notification Dated _____

☒ New CSF(s) Dated FEB 1 5 2012

☐ Other: _____

☒ Decision #: 454491

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Jessica Rogala

Phone: 347-0263 Division: RD/IRB

Date: MAR 2 6 2012



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

70552-2

Date of Issuance:

MAR 26 2012

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Methomyl Technical

Name and Address of Registrant (include ZIP Code):

Sinon Corporation
c/o Biologic, Inc. 115 Obtuse Hill Road
Brookfield, CT 06804

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

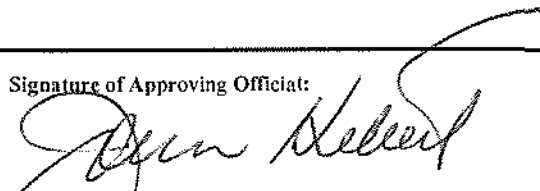
Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. Make the following label change before you release the product for shipment:

Revise the EPA Registration Number to read, "EPA Reg. No. 70552-2"

Signature of Approving Official:


John Hebert, Product Manager (07)
Insecticide-Rodenticide Branch, Registration Division (7505P)

Date:

MAR 26 2012

EPA Form 8570-6

3. The Basic Confidential Statement of Formula (CSF) dated February 15, 2012 , is acceptable.
4. **Note:** Should you wish to add a reference to the company's website on your label, please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, **regardless of whether a website is referenced on your product's label**, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.
5. Storage stability (830.63 17) and corrosion characteristics (830.6320) data must be submitted within 18 months from the date of this registration notice.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Per 40 CFR 156.10(6), submit one copy of your final printed labeling before you release the product for shipment. As defined in 40 CFR 152.3, "final printed labeling" means the "label or labeling of the product when distributed or sold." Clearly legible reproductions or photo reductions will be accepted for unusual labels. Note that a clean copy of the master label in most cases does not meet the definition of final printed labeling.

A stamped copy of the label is enclosed for your records. If you have any questions regarding this notice, please contact Jessica Rogala via e-mail at rogala.jessica@epa.gov or by telephone at (703) 347-0263.

John Hebert
Product Manager (07)
Insecticide-Rodenticide Branch
Registration Division (7505P)

Methomyl Technical

For Formulation Use Only

INGREDIENT STATEMENT

ACTIVE INGREDIENT:

Methomyl: S-Methyl N-[(methylcarbamoyl)oxy] thioacetimidate

By Weight

99.3%

INERT INGREDIENTS

0.7%

TOTAL

100.0%

EPA Reg. No. 70552-X

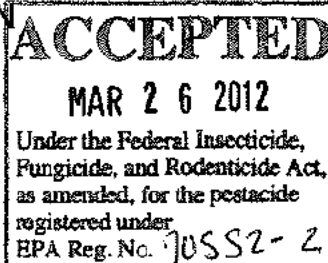
EPA Est. XXXXX-XXX-XXX

KEEP OUT OF REACH OF CHILDREN

DANGER



POISON



FIRST AID

THIS PRODUCT IS AN N-METHYL CARBAMATE INSECTICIDE.

If Swallowed:	Call a poison control center or doctor immediately for treatment advice. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.
If in Eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If Inhaled:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.
If on Skin or Clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN

ATROPINE IS AN ANTIDOTE - SEEK MEDICAL ATTENTION AT ONCE IN ALL CASES OF SUSPECTED POISONINGS. POISONING SYMPTOMS: Methomyl poisoning produces effects associated with anticholinesterase activity which may include weakness, blurred vision, headache, nausea, abdominal cramps, discomfort in the chest, constriction of pupils, sweating, slow pulse, muscle tremors.

TREATMENT: Atropine sulfate should be used for treatment. Administer repeated doses, 1.2 to 2.0 mg. intravenously every 10 to 30 minutes until full atropinization is achieved. Maintain atropinization until the patient recovers. Artificial respiration or oxygen may be necessary. Allow no further exposure to any cholinesterase inhibitor until recovery is assured. Do not use morphine or 2-PAM. However, for exposure to methomyl and organophosphorous insecticides, 2-PAM may be used as required to supplement the atropine sulfate treatment as described above. For medical emergencies involving this product, call toll free [enter phone number].

HOT LINE NUMBER

If poisoning symptoms appear (see POISONING SYMPTOMS), get medical attention. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also call [ENTER PHONE NUMBER] for emergency medical treatment information.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

FATAL IF SWALLOWED. MAY BE FATAL IF INHALED OR GETS IN EYES. DO NOT BREATHE DUST OR SPRAY MIST. DO NOT GET IN EYES, ON SKIN, OR ON CLOTHING. WEAR PROTECTIVE EYEWEAR AND RESPIRATOR. HARMFUL IF ABSORBED THROUGH THE SKIN. AVOID CONTACT WITH SKIN. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

IMPORTANT NOTICE TO HANDLERS

BEFORE OPENING DRUM PUT ON CHEMICAL PROTECTIVE CLOTHING, CHEMICAL RESISTANT GLOVES, SOCKS AND CHEMICAL RESISTANT FOOTWEAR, GOGGLES OR FACE SHIELD, AND A RESPIRATOR JOINTLY APPROVED BY THE MINE SAFETY AND HEALTH ADMINISTRATION AND BY THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH. WEAR CLEAN CLOTHING DAILY.

Technical information for this product is available from the manufacturer on request.

ENVIRONMENTAL HAZARD STATEMENT

This product is toxic to fish, birds and other wildlife. Keep out of any body of water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL AND CHEMICAL HAZARDS

Keep container closed. Use with adequate ventilation.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for obtaining EPA registration of their formulated product.

1. Only for formulation into end use insecticide products registered for the following:

Terrestrial Food Crops: Alfalfa, anise (fennel), apple asparagus, avocado, barley, beans (dried-type), beans (succulent), beets (roots and tops), bermudagrass, blueberry, carrot (roots and tops), chicory, corn (field), corn (pop), corn (sweet), corn (unspecified), cotton (unspecified), eggplant, garlic, grapefruit, groundcherry (strawberry tomato/tomatillo), horseradish, lemon, lentils, mint, nectarine, oats, onion, onions (green and bulb), orange, peach, peanuts (unspecified), pear, peas (field), peas (succulent), peas (unspecified), pecan, pepper, peppermint, pomegranate, potato (white/irish), radish, rye, sorghum (unspecified), soybeans (unspecified), spearmint, sugar beet, sweet potato, tangelo, tangerines, tomato, turnip (greens), vegetable, leafy, except brassica (Group 4; includes: amaranth, leafy, arugula, cardoon, celery, celery, Chinese, celtuce, chervil, chervil, fresh leaves, chrysanthemum, edible leaved, chrysanthemum, garland, corn salad, cress, garden, cress, upland, dandelion, leaves, dock, endive, fennel, Florence, fennel, Florence, fresh leaves and stock, kale, sea, lettuce, head, lettuce leaf (black seeded simpson, salad bowl, etc.), orach, orach, leaves, parsley, parsley, leaves, purslane, garden, purslane, winter, radicchio, rhubarb, spinach, spinach, Chinese, spinach, New Zealand, spinach, vine, swiss chard, tampala, vegetable, leafy), vegetable, brassica leafy (Group 5; includes: broccoli, broccoli raab, broccoli (Chinese), brussels sprouts, cabbage, cabbage (Chinese, bok choy), cabbage (Chinese, mustard), cabbage (Chinese, napa), cauliflower, collards, kale, kohlrabi, mustard (greens), mustard (spinach), rape greens), vegetable, cucurbit. (Group 9; includes: balsam apple, balsam pear, cantaloupe, chayote, fruit, cucumber, cucumber (Chinese), cucurbits, gherkin (west Indian), gourd (edible), melon, melon (citron), muskmelon, pumpkin, squash, squash (summer), squash (winter), watermelon, waxgourd (Chinese)), wheat.

Terrestrial Nonfood Crops: tobacco (excluding shade grown), tree nuts (non-bearing), turf. This product may be formulated into end use products for the indoor/outdoor non-food use sites listed below only if all the restrictions listed below apply to the registration of the end use product.

- a. No uses in or around homes or any other place where children are likely to be present.
- b. The end use product for these use sites will be limited to use in bait stations four feet off the ground, except

the end use products may be used as scatter bait only in EPA approved commercial agricultural production areas.

- c. An embittering agent must be added to all end use products at concentrations of at least 20-50 ppm.
 - d. End use products must be an EPA approved color.
 - e. All end use fly bait products must contain separate use directions for scatter bait and bait station uses. Indoor/Outdoor Nonfood Uses: dog kennels, fur-bearing animal units, farm buildings, poultry houses, commercial, industrial and institutional areas (outdoor), eating establishments (outdoor), food processing, handling and storage plants/areas (outdoor), garbage areas, garbage cans, trash bins, meat processing plants (nonfood areas), poultry processing plants (nonfood areas).
2. Uses for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.
3. Uses for experimental purposes that are in compliance with U.S. EPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store product only in original container, in a cool, dry industrial location inaccessible to children and pets. Do not use or store in or around the home.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Refer to the Net Contents section of this product's labeling for the applicable type of container designation. **Nonrefillable Containers:** Nonrefillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. Do not transport if this container is damaged or leaking. If the container is damaged, leaking or obsolete, or in the event of a major spill, fire or other emergency, contact the manufacturer at [enter phone number].

LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read this Limitation of Warranty and Liability Before Buying or Using This Product. If the Terms Are Not Acceptable, Return the Product at Once, Unopened, and the Purchase Price Will Be Refunded.

Sinon Corporation warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for the purpose stated in the directions under normal conditions. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, SINON CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL SINON CORPORATION OR SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

BUYER'S OR USER'S BARGAINED-FOR EXPECTATION IS CROP PROTECTION. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER AND THE EXCLUSIVE LIABILITY OF SINON CORPORATION OR SELLER, FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY OR CONTRACT, NEGLIGENCE, TORT OR STRICT LIABILITY), WHETHER FROM FAILURE TO PERFORM OR INJURY TO CROPS OR OTHER PLANTS, AND RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT, OR AT THE ELECTION OF SINON CORPORATION OR SELLER, THE REPLACEMENT OF THE PRODUCT.

To the extent consistent with applicable law that allows such requirement, buyer and all users shall promptly notify Sinon Corporation of any claims, whether based on contract, negligence, strict liability, other tort or otherwise, or be barred from any remedy. This Limitation of Warranty and Liability may not be amended by any oral or written agreement.

Net Contents: _____

Manufactured by:
Sinon Corporation
111, Chung-Shan Road
Ta-Tu Hsiang, Taichung Hsien 432
Taiwan, ROC



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70552-X	2. EPA Product Manager J. Hebert	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Methomyl Technical	PM# 7	
5. Name and Address of Applicant (Include ZIP Code) Sinon Corporation c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 352-366 Product Name DuPont Methomyl Technical	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application for a new pesticide product will fall within the category on Table 4 - Registration Division: New Products as published in the August 5, 2008 Federal Register. This product is further defined under EPA No. 310; CR No. 46. Sinon is submitting product chemistry data and using the cite-all option of data support for any data that may be applicable to this registration action. The PRIA fee for this application is \$4,807.

Jane Miller Tel: (203) 740-1200; Fax: (203) 740-1220; Email: jmill@biologicconsulting.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input checked="" type="checkbox"/> Paper	
				Other (Specify) HDPE	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 100 kg		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Jane M. Miller	Title Agent	Telephone No. (Include Area Code) 203-740-1200	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Agent		
4. Typed Name Jane M. Miller	5. Date August 30, 2011		

NOTE TO FILE:

Concerning #4 of DP 395129

1. Follow-up discussion with Shyam Mathur: Shyam agreed that the product could be registered. He said that the difference in impurity profile would allow the proposed product to rely on the generic data.
2. Discussion with Byron Backus: Byron does not see an issue with an impurity profile i.e. one different impurity compared to the me-too formulation because it is less than .01% from an acute toxicity perspective. The proposed product is able to rely on the acute data and acute tox profile for 352-366.

REQUEST FOR WORK TO BE DONE BY THE CONTRACTOR

- (1) Date: 12/08/11
- (2) Name of Contractor: SUMMITEC CORPORATION
- (3) Division: Registration
- (4) Task #: 3 - A - 155
- (5) EPA Requesting Reviewer Name: Linda Mascall Tele #: 703-308-9371
- (6) Product Name: Methomyl
- (7) CBI: YES ☒ NO ☐ FIFRA: YES ☒ NO ☐
- (8) Description for Each Study: (Identify the type of study to be evaluated, provide the information requested and describe the type of work to be performed if different from the following statement - be specific).

DP Barcode: 395129 P.C. Code: 090301

Decision #: 454491 Submission #: 903045

PRIA: ☒ FIFRA: ☐

Evaluate and prepare a DER for the following studies:

STUDY description	MRID #	Projected # Hrs.	Actual hrs used per MRID by Summitec
Group A	485970-01		
Group A	485970-02		
Group B	485970-03		
Group B	485970-04		
Group B	485970-05		
Group B	485970-06		
Group B	485970-07		
Group B	485970-08		
Group B	485970-09		
Group B	485970-10		
Group B	485970-11		
Group B	485970-12		
Group B	485970-13		
Total Number of Review Hours Assigned		20	

Approval:

[Signature]
Requesting Branch Chief/WAM

12-8-11
Date

[Signature]
Project Officer

12-8-2011
Date

Return to RD by Date: 1/12/12

Pages 11-20 Manufacturing process information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: 395129; **EPA Reg. No.:** 70552-E; **PRODUCT NAME:** Methomyl Technical;
DECISION No.: 454491; **PC Code(s):** 090301; **ACTION CODE:** R310; **FOOD USE:** Yes

Date: February 17, 2012

SUBJECT: Product Chemistry Review of Methomyl Technical (TGA)

FROM: Shyam Mathur
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

Signature
02/17/12

TO: Jessica Rogala / John Hebert RM07
Insecticide-Rodenticide Branch / RD (7505P)

Signature

DP BARCODE: 395129
DECISION No.: 454491
File Symbol No.: 70552-E
PRODUCT NAME: Methomyl Technical
PC Code: 090301
REGISTRANT: Sinon Corporation.
USE: Insecticide
FOOD USE: Yes ☒ No ☐
MRID Numbers: 485970-01 through 485970-13

INTRODUCTION:

The registrant has submitted an application for the registration for a new Methomyl Technical/mup, an insecticide, produced by Sinon Corporation at Taichung Hsien, Taiwan, ROC. The registrant has claimed that the proposed Methomyl technical/mup is substantially similar to DuPont Methomyl Technical (EPA Reg. No 352-366). In support of this application, the registrant has submitted 830 Series group A data (830.1550, 1600, 1620, 1670, 1700, 1750, and 1800) (MRID 485970-01) and 830 Series group B data (830.6302, 6303, 6304, 6313, 6314, 7000, 7050, 7200, 7300, 7370, 7550, 7570, 7840, 7860, 7950) (MRID 485970-03 to 485970-13). The registrant submitted a basic CSF dated August 31, 2011. On the advice of the Agency the registrant submitted a revised basic CSF (dated 02-15-12) on February 16, 2012. Summitec Corporation of Knoxville, TN conducted primary review on the product chemistry data. TRB has been asked to evaluate the product chemistry data submitted and determine the acceptability of the proposed basic CSF & the supporting product chemistry data and also determine similarity to the cited product.

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

SUMMARY OF FINDINGS:

1. 830 Group A series guidelines:

830.1550 (product identity & composition): The registrant has submitted data identifying the product (TGA) by common name, CAS name, molecular weight, and structural formula (MRID 485970-01). Chemical analysis showed that the product is 99.02% to 99.46% pure. The product chemistry data submitted corresponding to guideline reference (830.1550) satisfy the requirements outlined in 40 CFR 158.320.

830.1600 (description of materials used to produce the product): The registrant has identified all the starting materials to be used in the production of the TGA and provided an MSDS for each starting material. The product chemistry data submitted corresponding to the guideline reference 830.1600 (description of materials used to produce the product) satisfy the data requirements of 40 CFR 158.325. The description of the materials used to produce the product is outlined in MRID 485970-01.

830.1620 (description of production process): The registrant has described each step in the production process for the manufacture of the TGA, the reaction scheme at each step, and the recovery of the intermediate and final product. Flowcharts of the process were also provided. The registrant provided information on the quality control measures, inspection of equipment, and equipment cleaning procedure. The consistently high purity of the TGA indicates that the product is of high quality. The production process is described in MRID 485970-01. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) satisfy the data requirements for 40 CFR 158.330.

830.1670 (discussion on the formation of impurities): The registrant identified the known and potential impurities and discussed the steps, reactions, and conditions that could generate the impurities (MRID 485970-01). The registrant on February 16, 2012 via e-mail provided additional explanation on few of the impurities present in the proposed product (see attachment). One of the impurities reported on the revised basic CSF is of tox concern and was not present in the registered product. The product chemistry data submitted corresponding to guideline reference 830.1670 (description of formation of impurities) satisfy the data requirements for 40 CFR 158.340.

830.1700 (preliminary analysis): The registrant analyzed five production batches and described the method for analyzing Methomyl Technical. Methomyl active ingredient was analyzed by high performance liquid chromatography with diode array detection (DAD) (HPLC-DAD). The impurities were analyzed by HPLC-DAD, gas chromatography-mass spectrometry (GC-MS), and nuclear magnetic resonance (NMR). Moisture content was determined by Karl Fischer titration. The preliminary analysis is described in MRID 485970-02. The product chemistry data submitted corresponding to guideline reference 830.1700 (preliminary analysis) satisfy the data requirements for 40 CFR 158.345.

830.1750 (certified limits): The proposed certified limits for the active ingredient and impurities are based upon the standard certified limits. The product chemistry data submitted corresponding to guideline reference 830.1750 (certified limits) satisfy the data requirements for 40 CFR 158.350.

830.1800 (enforcement analytical method): The validation of the analytical method is described in MRID 485970-02. The HPLC-DAD method for analysis of the active ingredient was validated based on accuracy, specificity, precision, and linearity. The HPLC-DAD method for the analysis of impurities was validated for precision, accuracy, specificity, limit of detection (LOD) and limit of quantitation (LOQ). The analytical method can be used to confirm the certified limits of Methomyl Technical. The product chemistry data submitted corresponding to guideline reference 830.1800 (enforcement analytical method) satisfy the data requirements for 40 CFR 158.355.

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

2. 830 series group B guidelines (physical-chemical properties):

Applicable physical-chemical data (830.6302-7950) were submitted by the registrant. The registrant submitted data for color, physical state, odor (MRID 485970-03), melting point (MRID 485970-04), density (MRID 485970-05), solubility in water (MRID 485970-06), dissociation constant (MRID 485970-07), partition coefficient (MRID 485970-08), pH (MRID 485970-09), stability at normal and elevated temperatures, metals and metal ions (MRID 485970-10), oxidation/reduction (MRID 485970-11), UV absorption (MRID 485970-12), and vapor pressure (MRID 485970-13). The physical-chemical data are summarized in Table 2.

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for Methomyl Technical and has concluded that:

1. All product chemistry data submitted for guideline 830 Series group A are acceptable.
2. The proposed revised CSF for the basic formulation (dated 02-15-12) is acceptable. One of the impurities reported on the revised basic CSF is of tox concern and was not present in the registered product.
3. The product chemistry data corresponding to 830 series group B are acceptable. These data are summarized in Table 2.
4. The proposed product (File Symbol No. 70552-E) was determined not to be substantially similar to the cited product with Reg. No. 352-366 from the product chemistry point of view due to different impurity profile.

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

830.1550: Product identity & composition (MRID No. 485970-01):

Common Name: Methomyl Technical

Chemical name:

CAS Name: S-methyl-N-[(methylcarbonyl)oxy]thioacetimidate

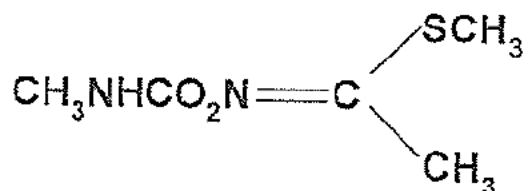
CAS No.: 16752-77-5

PC Code No.: 090301

Empirical Formula: $C_5H_{10}N_2O_2S$

Molecular Weight: 162.2

Structural Formula:



DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

Table 1. Manufacturing and Impurity Data for Methomyl Technical				
GLN	Requirement	MRID	Status	Details and/or Deficiency
830.1550	Product Identity and composition	485970-01	A	The TGA1 was identified and the identity was confirmed by comparison with Methomyl standard.
830.1600	Description of materials used to produce the product	485970-01	A	The starting materials used to produce the TGA1 along with the specification, suppliers, and MSOS are presented for each starting material.
830.1620	Description of production process	485970-01	A	The production process is described along with quality control measures that included a description of the equipment inspection procedures and cleaning of equipment.
830.1670	Discussion of formation of impurities	485970-01	A	The registrant identified the actual and theoretical impurities formed during the production process, the step in the process where they are formed, and methods to minimize the formation of impurities. Additional information provided in the e-mail letter dated 02-15-12 (see attachment on next page).
830.1700	Preliminary analysis	485970-02	A	The registrant analyzed five production batches of the TGA1. The active ingredient was analyzed by HPLC-DAD, and impurities by HPLC-DAD, GC-MS, and NMR. [REDACTED] content was analyzed by Karl Fischer titration.
830.1750	Certified limits	485970-01 CSF	A	The proposed certified limits for the TGA1 are based upon the standard certified limits.
830.1800	Enforcement analytical method	485970-02	A	The enforcement analytical method is HPLC-DAD, which is the same as used for the preliminary analysis. The analytical methods for measuring the active ingredient and impurities were validated for precision, accuracy, linearity, and specificity along with LOC and LOQ for impurities.
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ; U = Up-grade (additional information required);				

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

Explanation for few of the minor impurities in Methomyl technical provided by the registrant by e-mail on 02-16-12:



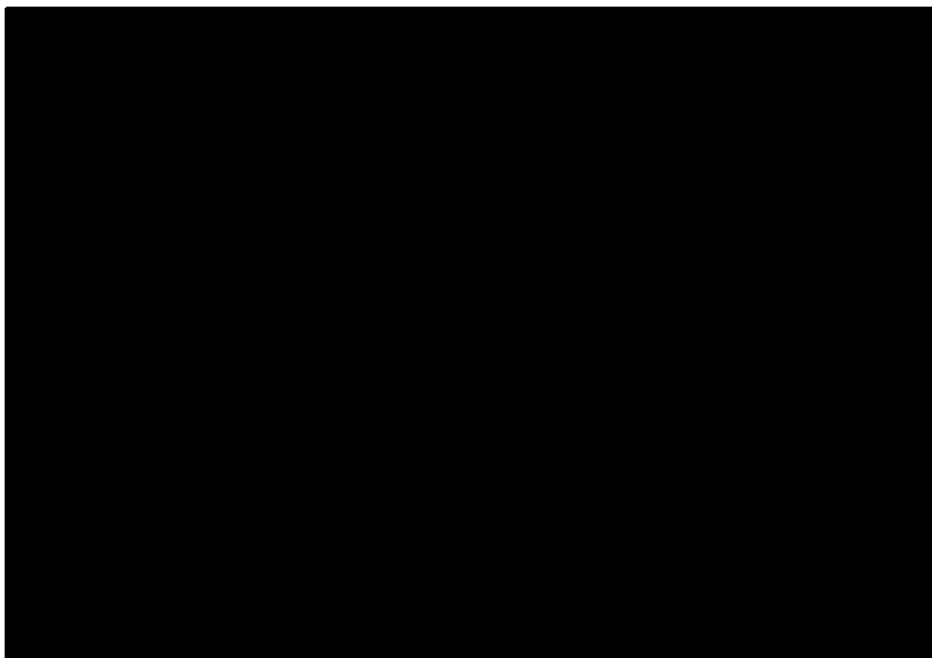
Sinon Methomyl Technical
Lawrence A. Miller
to:
Shyam Mathur
02/15/2012 12:46 PM
Cc:
"sinonusa", "rebecca", "Peter Su"
Hide Details
From: "Lawrence A. Miller" <lmliller@biologicconsulting.com>

To: Shyam Mathur/DC/USEPA/US@EPA

Cc: "sinonusa" <sinonusa@earthlink.net>, "rebecca" <rebecca@sinon.com.tw>, "Peter Su" <PETERSU@sinon.com.tw>

Hi Shyam:

Further to our most recent telephone conversations re: Sinon's Methomyl Technical;
EPA file Symbol 70552-E, please note the following responses to your questions:



Please give me a call if you need any additional information.

Best Regards,

Larry -

Lawrence A. Miller
BIOLOGIC, Inc.
115 Obtuse Hill Road
Brookfield, CT 06804

Tel: (203) 740-1200
Fax: (203) 740-1220
Email: lmliller@biologicconsulting.com

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
 DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

830 Series Subgroup B (Physical-Chemical Properties) for Methomyl Technical (Batch WGF0211)

Table 2: Physical and Chemical Properties of Methomyl Technical				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	485970-03	A	Methomyl Technical is off-white in color
830.6303	Physical state	485970-03	A	Methomyl Technical is a crystalline solid @ 25°C
830.6304	Odor	485970-03	A	Methomyl Technical has a mild characteristic odor
830.6313	Stability to normal and elevated temperatures, Stability to metals, and metal ion	485970-10	A	The TGA is stable after storage at an elevated temperature (54°C) for up to 14 days. The TGA is stable after contact with metal or metal ions at 54°C for up to 14 days
830.6314	Oxidation/reduction: chemical incompatibility	485970-11	A	The TGA showed no reactivity when in contact with water, 10% monoammonium phosphate, iron powder, or kerosene for 24 hours, but was incompatible when in contact with 10% potassium permanganate for 24 hours.
830.6315	Flammability		N/A	The TGA is a solid
830.6316	Explosibility		N/A	Not required for TGA
830.6317	Storage stability		N/A	Not required for TGA
830.6319	Miscibility		N/A	The TGA is not an emulsifiable liquid
830.6320	Corrosion characteristics		I	Study is in progress
830.7000	pH	485970-09	A	pH = 5.88 (1% w/v solution @ 26.2°C ~ 26.4°C)
830.7050	UV/Visible absorption	485970-12	A	Neutral solution: 234.0 nm (ϵ = 9051.7), pH 6.95; Basic solution: 237.0 nm (ϵ = 6209.1), pH 12.85; Acidic solution: 234.0 nm (ϵ = 8945.6), pH 0.92
830.7100	Viscosity		N/A	The TGA is a solid at room temperature.
830.7200	Melting point	485970-04	A	78.6°C
830.7220	Boiling point	485725-03	N/A	TGA is not a liquid at room temperature
830.7300	Density (bulk)	485970-05	A	0.8352 g/mL @ ambient temperature
830.7370	Dissociation constants in water (DC)	485970-07	A	No pKa was found
830.7550	Partition coefficient	485970-08	A	$\log P_{ow}$ (25°C) = 0.12 @ pH 4, 0.15 @ pH 7 and 9
830.7840	Water solubility	485970-06	A	52.06404 g/L @ pH 4, 50.80128 g/L @ pH 7, 52.38273 g/L @ pH 9, 20°C
830.7950	Vapor pressure	485970-13	A	1.45×10^{-3} Pa at 21.0°C, 3.68×10^{-3} Pa @ 30.9°C, 1.56×10^{-2} Pa @ 40.1°C
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ; U = Up-grade (additional information required); W = waivers				

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
 DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

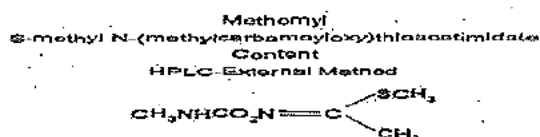
830.1800 (enforcement analytical method):

The HPLC/DAD validated method (LCM10) for analyzing Methomyl is presented below along with representative chromatograms of the Methomyl standard and Methomyl Technical. This method was used for the five batch analysis of Methomyl Technical. The method was validated for precision, accuracy, specificity, and linearity.

Validated Analytical Method

Effective Date: Sep. 15, 2009	Code: LCM10	Revision No.:	Page 2 of 6
Subject: Methomyl(CIPAC 264/TC/(M)/-)			

1. Information:



Empirical formula: $\text{C}_5\text{H}_{10}\text{N}_2\text{O}_3\text{S}$

Molecular weight: 162.2 g/mole

2. Scope

This method is applicable to the analysis of Methomyl in technical active ingredient and in formulated products and in processes of the specific test items (Solubility in water - Hydrolysis - Vapor Pressure)

3. Principle

The weight percentage is determined by high performance liquid chromatography using an external standard technique.

4. Reagents

- 4.1 Analytical standard of Methomyl
- 4.2 Methanol HPLC grade (Lichrosolv, Merck)
- 4.3 Acetonitrile HPLC grade (Lichrosolv, Merck)
- 4.4 D. I. Water obtained with a Millipore Milli-Q system. The filter-sterilized water typically has greater than 18.7 Mohm-cm resistivity.

Validated Analytical Method

Effective Date: Sep. 15, 2009	Code: LCM10	Revision No.:	Page 3 of 6
Subject: Methomyl(CIPAC 264/TC/(M)/-)			

5. Apparatus

- 5.1 Hewlett Packard 1100 series LC with an UV detector and autosample injector, or equivalent.
- 5.2 Hewlett Packard LC ChemStation, or equivalent.
- 5.3 Merck Lichrospher 100 RP-18, 5µm, L:25.0 cm ID:4.0 mm

6. Chromatographic conditions

- 6.1 Column : Merck Lichrospher 100 RP-18, 5µm, L:25.0 cm ID:4.0 mm
- 6.2 Mobile phase : 8.5:91.5(v/v) Acetonitrile:D.I.Water
- 6.3 Column temperature : 45°C
- 6.4 Flow rate : 2.6 ml/min
- 6.5 Detection wavelength : 254 nm
- 6.6 Injection volume : 10 µl
- 6.7 Solvent : Methanol
- 6.8 Retention time : Methomyl 5.1 min.

7. Procedure

- 7.1 Preparation of calibration standards (If necessary, you can prepare another calibration standards according your requirement)

Prepare Methomyl standard substance, accurately to 0.1 mg, to a suitable volumetric flask and dilute with solvent (6.7) to the mark, producing a stock solution and homogenize with ultrasonic bath. Calibration standard solutions are prepared by the stock solution.

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
 DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

Validated Analytical Method

Effective Date: Sep. 15, 2009	Code: LCM10	Revision No.:	Page 4 of 6
Subject: Methomyl(CIPAC 264/TCI(M)-)			

Calibration standard solutions	Methomyl conc. (ppm)
STD-1	168.07
STD-2	336.15
STD-3	504.22
STD-4	672.29
STD-5	840.37

7.2 Preparation of sample solution (If necessary, you can prepare another calibration standards according your requirement)
 Prepare the test substance containing Methomyl within calibration curve, e.g. approx. STD-3 of Methomyl in section 7.1. Clarify part of the sample solution with 0.45 µm filter, if turbidity occurs.

7.3 Quality control (Q.C.) samples
 Prepare Methomyl standard substance containing approx. conc. of STD-2 for QC-1 and conc. of STD-4 for QC-2

7.4 Analysis of sample solution
 Inject standard and sample solutions into the chromatograph using the conditions described in Section 6. All standard and sample solutions are injected duplicate and the peak area for each injection recorded. The content of Methomyl is determined using the calibration procedures in section 8.

Validated Analytical Method

Effective Date: Sep. 15, 2009	Code: LCM10	Revision No.:	Page 5 of 6
Subject: Methomyl(CIPAC 264/TCI(M)-)			

8. Calculation

The following equations were used to calculate measured concentrations:

$$\frac{(\text{signal} - b)}{m} = DC$$

$$DC \times V / W \times 100\% = A\%$$

Where:

signal = ratio of peak signal (area) from chromatogram
 b = y-intercept from regression analysis
 m = slope from regression analysis
 DC = detected concentration in the sample by HPLC
 A = analytical result (w/w)
 W = sample weight (mg)
 V = Dilute volume (L)

9. Note

- 9.1 The stable response factor means the linear correlation coefficient (r) is more than 0.99.
 9.2 Quality control samples prepared and analyzed along with the test samples should be within the range $\pm 2.5\%$ of the prepared concentration.

10. Chromatogram (see Figure 1)

11. Reference

CIPAC METHOMYL 264

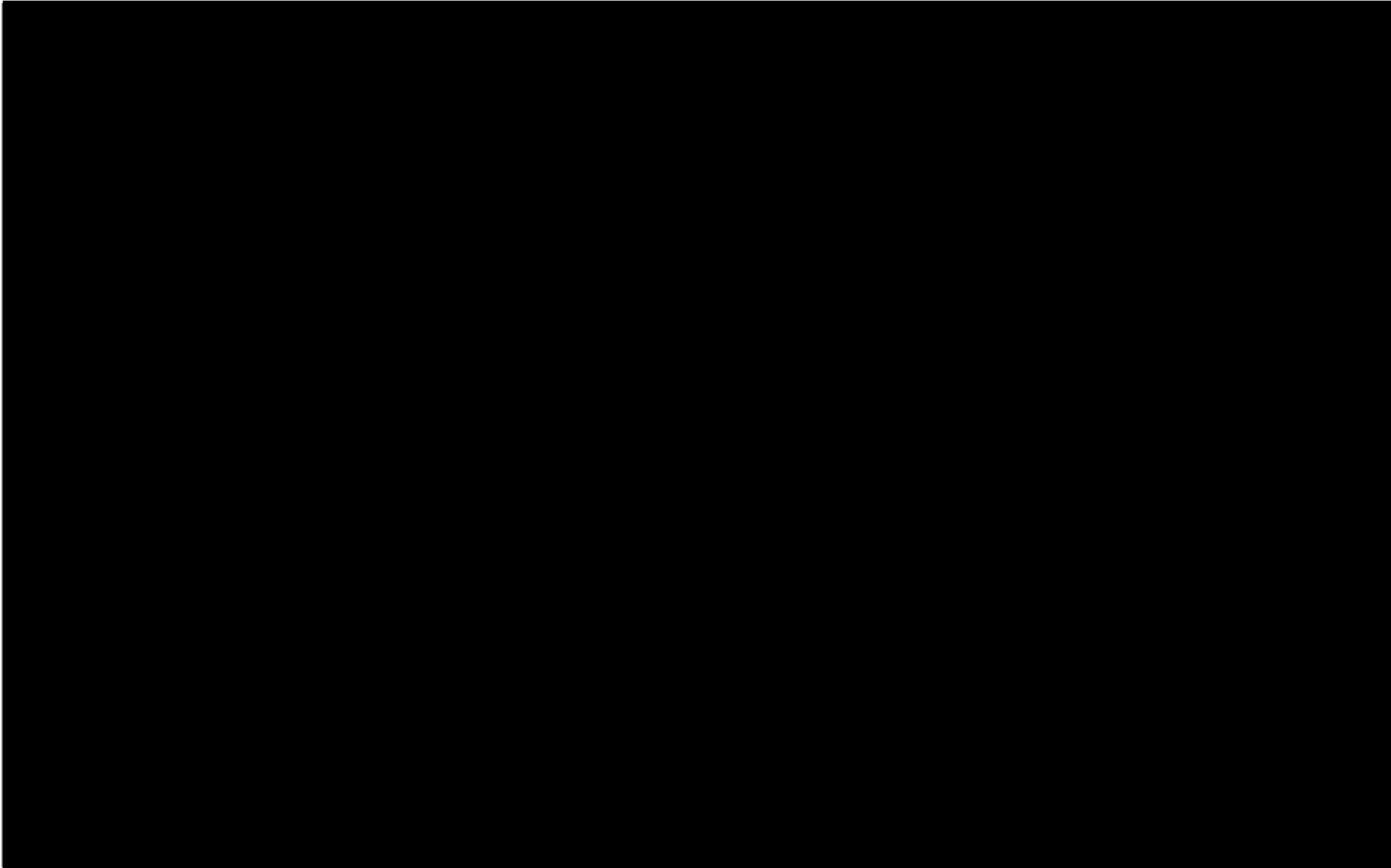
Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

CONFIDENTIAL APPENDIX

830.1600 (description of materials used to produce the product): MRID 485970-01

The following list of materials, including their CAS Registry Number, the name and address of each supplier, the assay and other relevant specifications, are utilized by Sinon Corporation for the production of its technical grade methomyl:



Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

CONFIDENTIAL APPENDIX

830.1620: Description of production process (MRID 485970-01)



Manufacturing process information may be entitled to confidential treatment

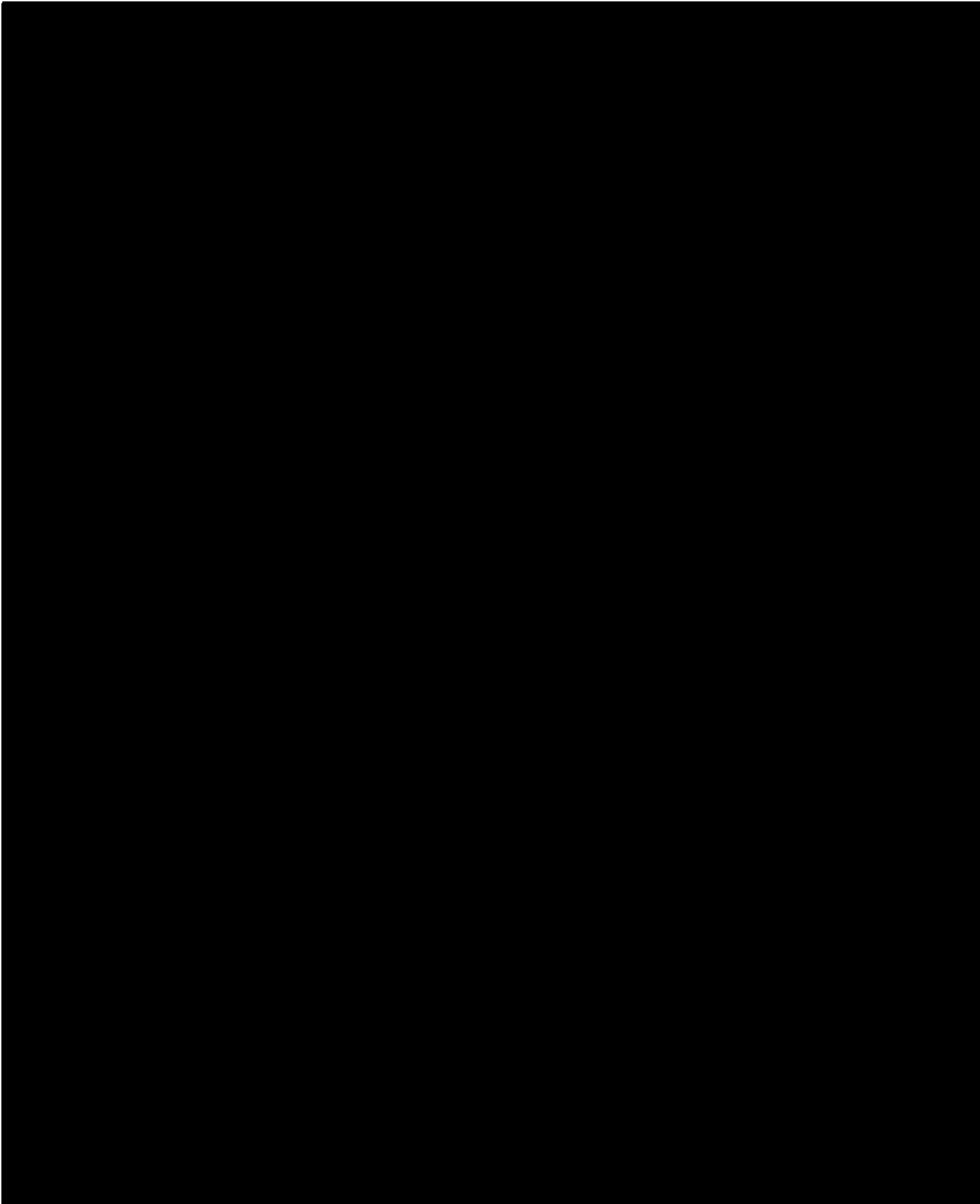
DP BARCODE No.: 395129; **EPA Reg. No.:** 70552-E; **PRODUCT NAME:** Methomyl Technical;
DECISION No.: 454491; **PC Code(s):** 090301; **ACTION CODE:** R310; **FOOD USE:** Yes

Process Equipment



Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

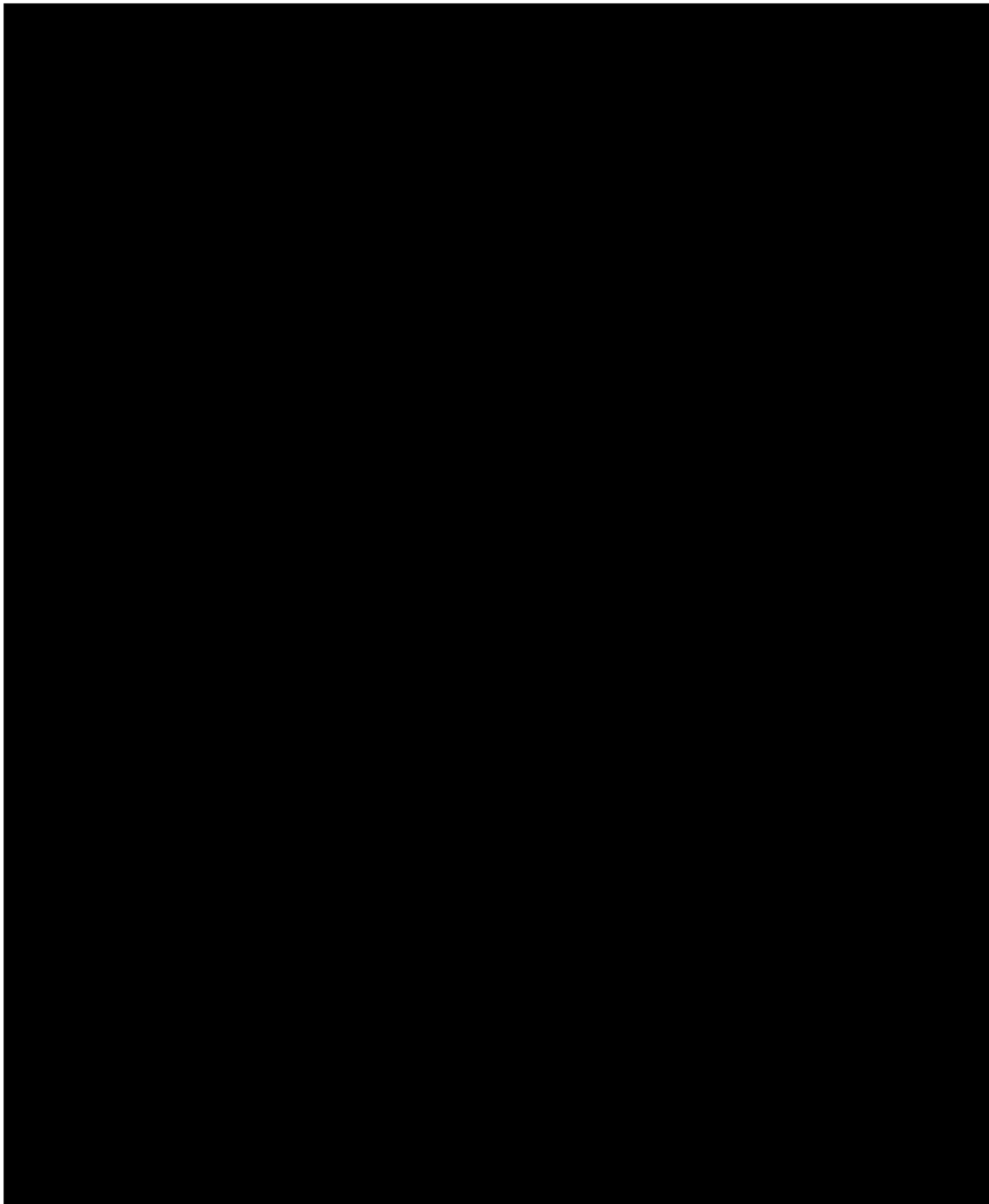


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DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes



Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

830.1700: Preliminary analysis (MRID 485970-02)

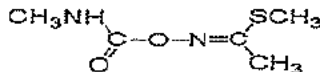
Five batch analysis of active ingredient in Methomyl Technical is presented below:

Test Substance:

Sinon Central Laboratory received 5 batches of the test substance, technical grade of Methomyl, from Sinon Corporation on Aug. 27, 2009. The test substance was stored at ambient temperature in a dark, ventilated cabinet.

The following information was provided by the sponsor:

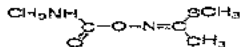
Empirical Formula:	C ₅ H ₁₀ N ₂ O ₂ S
Chemical Name:	S-methyl N-(methylcarbamoyloxy)thioacetimidate
Physical Appearance:	Off white crystals
Molecular Weight:	162.2 g/mole
CAS Registry No.:	16752-77-5
Batch No.:	WGF0151, WGF0181, WGF0191, WGF0211, WGF0231
Expiry date:	Jul., 2011
Chemical Structure:	



Analytical Reference Standard:

The reference substance of Methomyl was received from sponsor. These reference standard was stored in a refrigerator (ca. 0-10°C). The Certificate of Analysis for the reference standard is shown in Appendix 1. The sponsor provided the following information.

Name:	Methomyl
Chemical Name:	S-methyl N-(methylcarbamoyloxy)thioacetimidate
Molecular Weight:	162.2 g/mole
CAS Registry No.:	16752-77-5
Batch No.:	G2098060503
Purity:	99.1%
Expiry date	Jul. 2011



Section 3.

Validation and Quantitation of Methomyl

3.1 Test Procedures:

3.1.1 Reagents and Test Equipment:

3.1.1.1 Reagents

All aqueous solutions were prepared using de-ionized water (meeting ASTM Type IIA requirements) obtained from a Millipore Milli-Q system. The filter-sterilized water typically shows greater than 16.7 Mohm-cm resistivity.

All the reagents used in this study are at least reagent grade and obtained from well-known commercial sources

Acetonitrile	: HPLC grade (Lichrosolv Merck)
Methanol	: HPLC grade (Lichrosolv Merck)

3.1.1.2 Test Equipment:

HPLC system:	Agilent, Model 1100 series
Autosampler:	Agilent, Model 1100 series
Degasser:	Agilent, Model 1100 series
Detector:	Agilent, Model 1100 series
Pump:	Agilent, Model 1100 series
Data acquisition system:	Agilent, LC ChemStation Rev. A10.02 and A10.03

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
 DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

Analytical balance: Mettler-Toledo, Model AG 135
 Pure water system: Millipore Academic A-10
 Electronic repetitive pipette: Brand HandyStep electronic
 Ultra Sonic bath: Power Sonic 510
 Fume hood
 General laboratory glassware

3.1.3 Five Batches Analysis

3.1.3.1 Methomyl Content

Duplicate aliquots (ca 50 mg) from each of five batches of technical grade Methomyl at 25 mL of Methanol to the mark, producing a sample solution. Homogenize with shaking. Accurate 3.0 ml of the solution above was pipetted into a 20 ml volumetric flask and dilute with Methanol to the mark. Active ingredient content employing Method No. LCM10 (see Appendix 2).

3.1.3.1.1 Preparation of Calibration Solutions

Calibration standard solutions were then subjected to High Performance Liquid Chromatography analysis according to the conditions described in Method No. LCM10 and the preparations of calibration standard solutions were described in section 3.1.2.1.1.

3.1.3.1.2 Preparation of QC Solutions

Weigh the Methomyl standard (24.5 mg) to a 25 ml volumetric flask and dilute with Methanol to the mark, producing a QC stock solution. Homogenize with shaking. Accurately add aliquots of the QC stock solution (2 and 4 ml) to each volumetric flask (10 ml). Make up to volume with Methanol, Producing a series concentration of QC-1 and QC-2 are for QC solutions.

Results of the five batch analysis of the active ingredient in Methomyl Technical (MRID 485970-02)

Results of five batch analysis for the active ingredient contents are given in the following table.

Table 6 Analytical Results of Methomyl Technical

Sub sample		Weight of sample (mg)		Area of sample*				Conc. of sample (mg/L)			
Description		1st	2nd	1st		2nd		1st		2nd	
				Rep.1	Rep.2	Rep.1	Rep.2	Rep.1	Rep.2	Rep.1	Rep.2
Batch No.	WGF0151	52.2	50.8	823.33557	807.74603	799.67070	797.37329	312.84	309.87	303.78	302.90
	WGF0161	59.3	60.1	930.45392	929.80240	942.17499	944.27996	353.88	353.69	358.37	359.18
	WGF0191	54.5	60.8	854.83911	863.67446	862.61440	948.62350	324.91	324.43	362.33	360.86
	WGF0211	61.0	58.9	958.31897	958.63867	876.02838	881.65790	364.55	364.66	333.03	339.02
	WGF0231	57.0	56.7	899.21698	899.26901	921.82463	920.90228	341.53	338.10	360.57	350.22

Description		Content of sample (w/w)				Average content (w/w) (n=4)*	SD (n=4)*	RSD (n=4)*
		1st		2nd				
		Rep.1	Rep.2	Rep.1	Rep.2			
Batch No.	WGF0151	99.80%	97.98%	99.66%	99.38%	99.23%	8.6.E-03	0.864%
	WGF0161	99.46%	99.40%	99.36%	99.60%	99.40%	1.0.E-03	0.102%
	WGF0191	99.36%	99.21%	99.65%	99.23%	99.30%	2.0.E-03	0.204%
	WGF0211	99.80%	98.64%	97.56%	99.30%	99.02%	9.9.E-03	1.005%
	WGF0231	99.66%	98.80%	99.54%	99.44%	99.42%	4.2.E-03	0.426%

*Value maybe varied due to rounding

Manufacturing process information may be entitled to confidential treatment

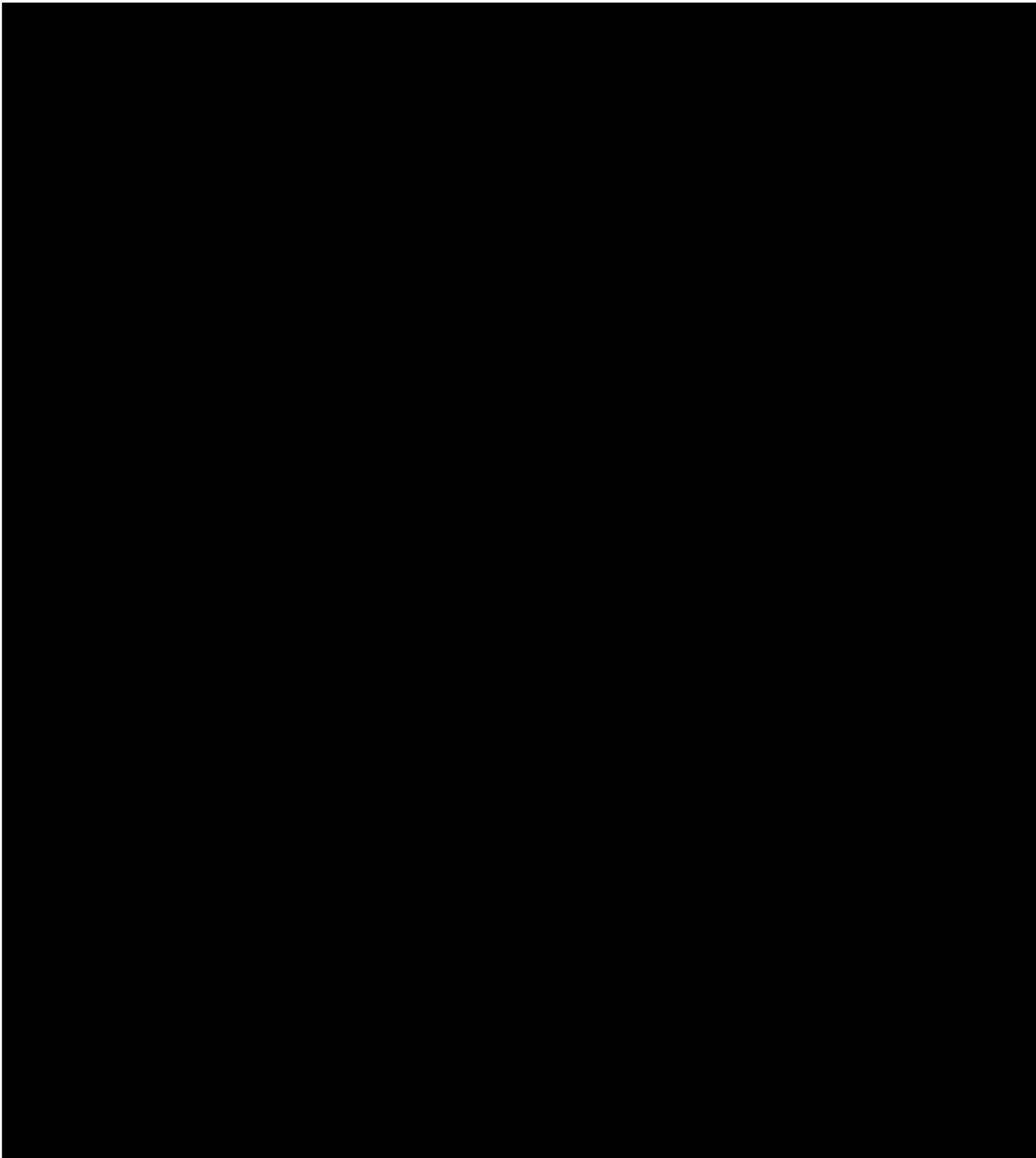
DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

Determination of Impurities in Methomyl technical (MRID No. 485970-02)



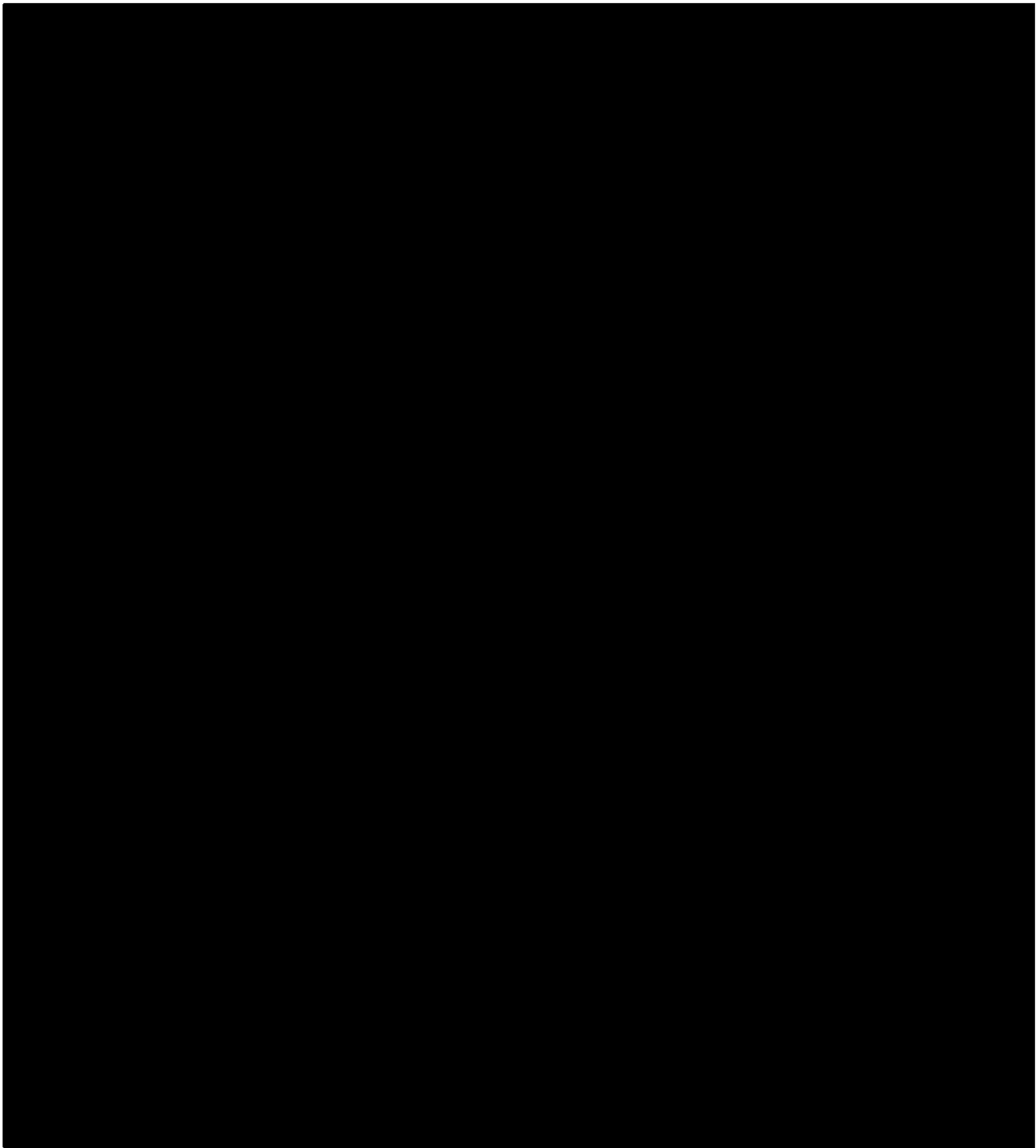
Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes



Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes



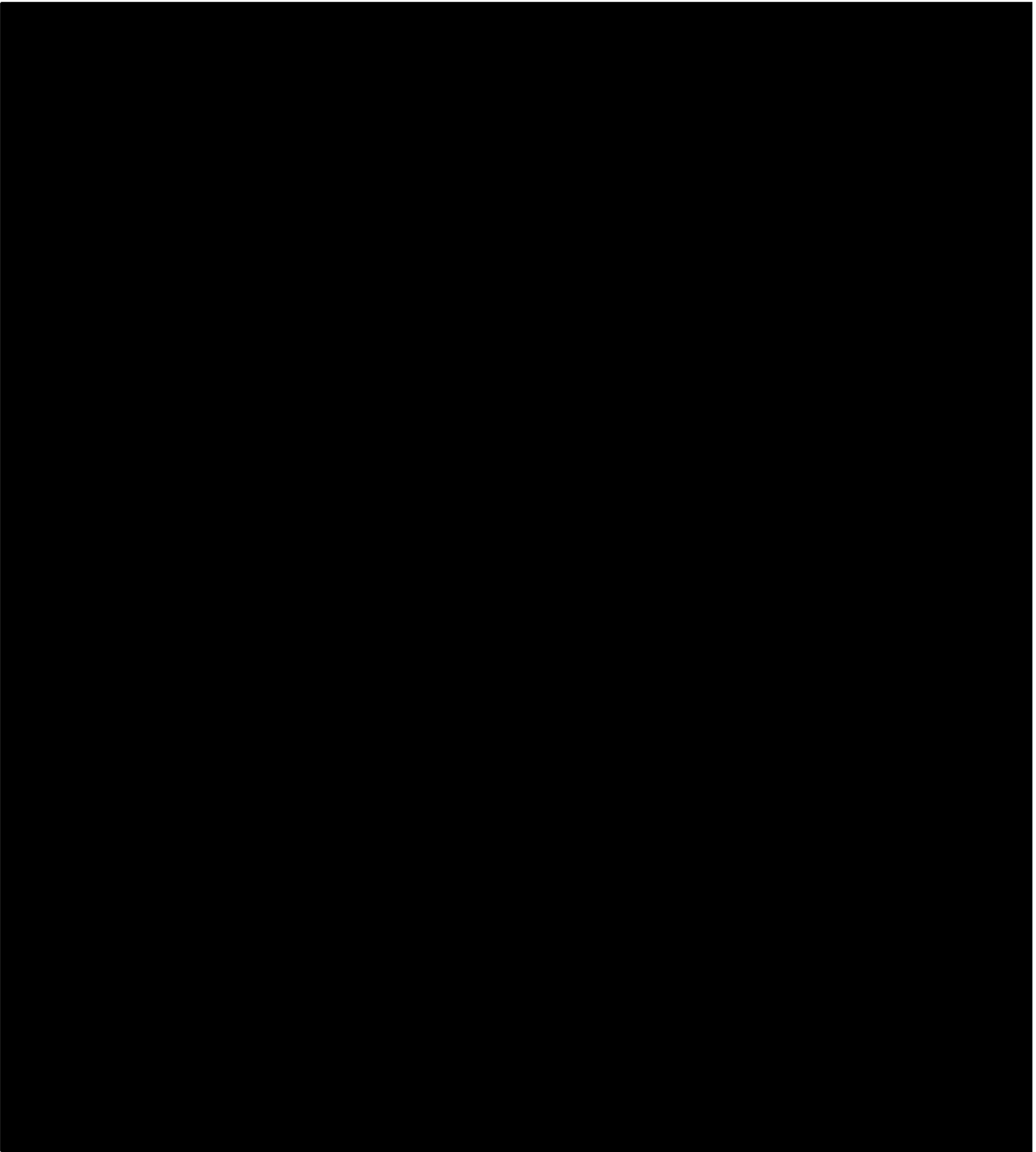
Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

Results of the five batch analysis of impurities in Methomyl Technical (MRID 485+70-02):

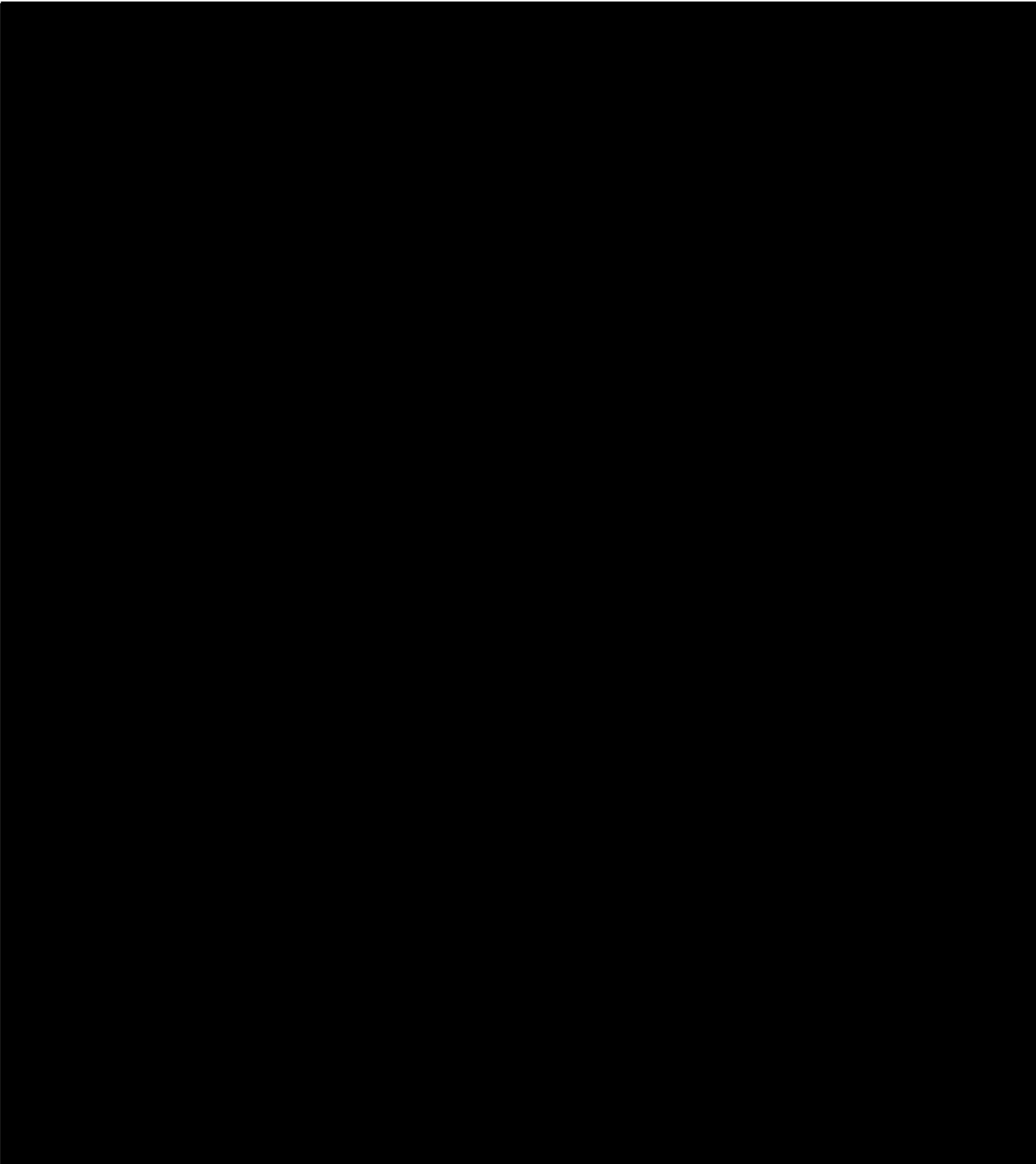
Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes



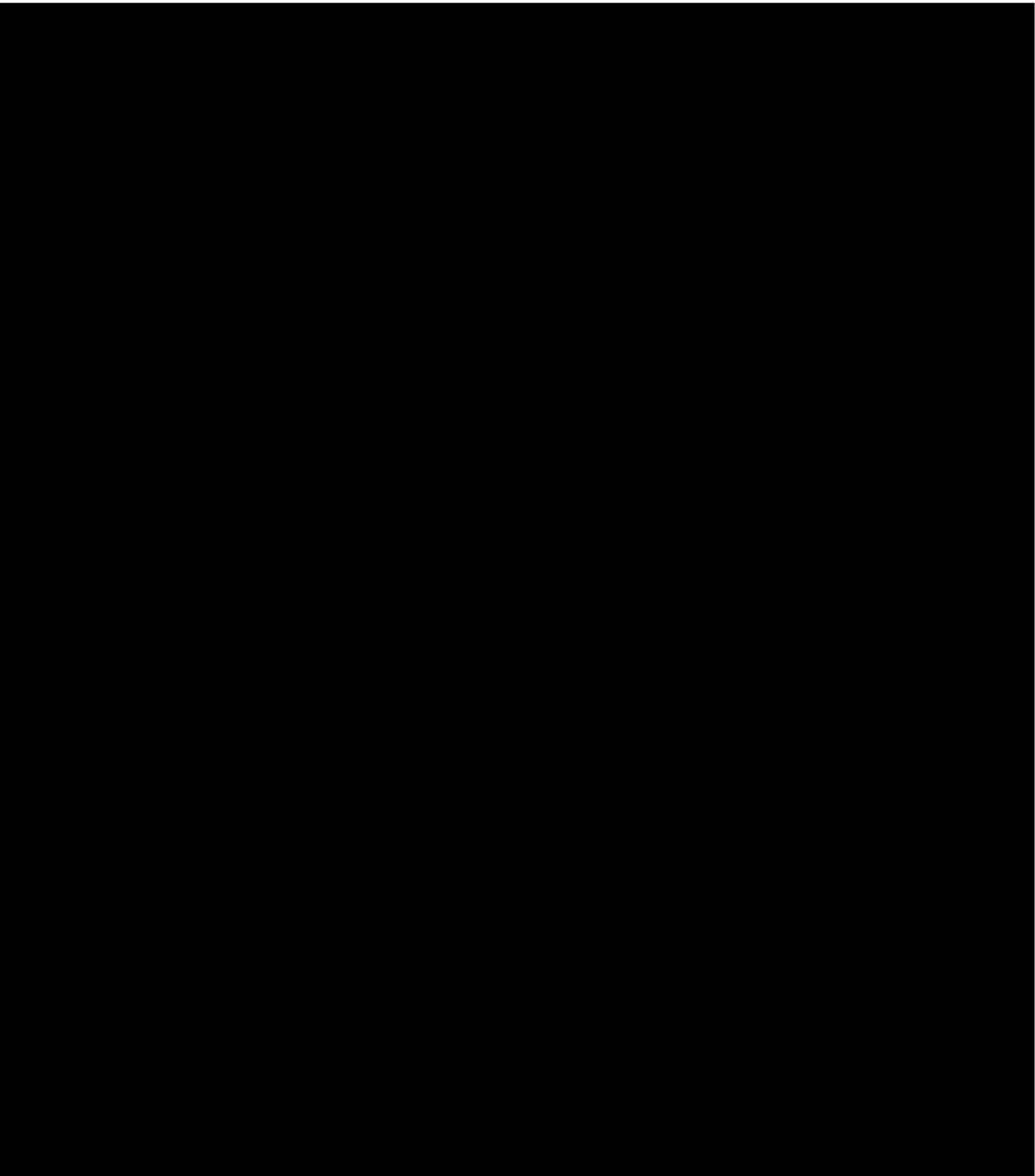
Manufacturing process information may be entitled to confidential treatment

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DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes



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DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes



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DP BARCODE No.: 395129; EPA Reg. No.: 70552-E; PRODUCT NAME: Methomyl Technical;
DECISION No.: 454491; PC Code(s): 090301; ACTION CODE: R310; FOOD USE: Yes

CONFIDENTIAL APPENDIX



DATA EVALUATION RECORD

METHOMYL TECHNICAL

STUDY TYPES: Product Identity and Composition (OPPTS 830.1550)
Description of Materials Used to Produce the Product (OPPTS 830.1600)
Description of Production Process (OPPTS 830.1620)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.6314, 830.7000,
7050, 7200, 7300, 7370, 7550, 7570, 7840, 7860, 7950)

MRIDs: 485970-01 through 485970-13

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Summitec Corporation
9724 Kingston Pike, Suite 602
Knoxville, Tennessee 37922

Task Order No. 3-A-155

Primary Reviewer:
Kowetha D. Mack, Ph.D., D.A.B.T.

Signature: KD Mack
Date: JAN 11 2012

Secondary Reviewers:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: JAN 11 2012

Program Manager:
Robert H. Ross, M.S., Program Manager

Signature: Robert H. Ross
Date: JAN 11 2012

Quality Assurance:
Angie M. Edmonds, B.S.

Signature: Angie M. Edmonds
Date: JAN 11 2012

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Summitec Corporation for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 19, 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

BIOLOGIC, INC.
SINON CORPORATION
115 OBTUSE HILL ROAD
BROOKFIELD, CT 06804

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 07-SEP-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

September 1, 2011

Mr. John D. Hebert
Product Manager, PM Team 7
Insecticide-Rodenticide Branch
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

SUBJECT: "Methomyl Technical"; EPA File Symbol: 70552-XXX.

Dear Mr. Hebert:

With this letter, we are submitting an application on behalf of Sinon Corporation for the registration of "Methomyl Technical". Please be advised that this application is submitted as a "me-too" registration, and is supported by the cite-all option in accordance with FIFRA 3(c)(1)(D).

In order for the Agency to make its determination of "substantial similarity", and to facilitate the processing of this application, please find the following enclosures:

Volume 1 – Administrative Materials:

- Transmittal Letter
- Application for Pesticide Registration; (EPA Form 8570-1).
- Certification with Respect to Citation of Data (EPA Form 8570-34).
- Data Matrix; (EPA Form 8570-35).
- Confidential Statement of Formula; (EPA Form 8570-4).
- Draft Labeling; (Five Copies).

Volume 2 – Manufacturing Process (Three Copies): 48597001

- Product Identity and Composition; (OPPTS 830.1550).
- Description of Materials Used to Produce the Product; (OPPTS 830.1600).
- Description of Production Process; (OPPTS 830.1620).
- Discussion of Formation of Impurities; (OPPTS 830.1670).

Volume 3 – Five-Batch Analysis (Three Copies):

48597002

- Preliminary Analysis; (OTTPS 830.1700).
- Certified Limits; (OPPTS 830.1750).
- Enforcement Analytical Method; (OPPTS 830.1800).

Volume 4 – Physical and Chemical Properties (Three Copies):

48597003

- Color; (OPPTS 830.6302).
- Physical State; (OPPTS 830.6303).
- Odor; (OPPTS 830.6304)

Volume 5 – Physical and Chemical Properties (Three Copies):

48597004

- Melting Point; (OPPTS 830.7200).

Volume 6 – Physical and Chemical Properties (Three Copies):

48597005

- Density; (OPPTS 830.7300).

Volume 7 – Physical and Chemical Properties (Three Copies):

48597006

- Water Solubility; (OPPTS 830.7840/7860).

Volume 8 – Physical and Chemical Properties (Three Copies):

48597007

- Dissociation Constant; (OPPTS 830.7370).

Volume 9 – Physical and Chemical Properties (Three Copies):

48597008

- Octanol/Water Partition Coefficient; (OPPTS 830.7550/7570).

Volume 10- Physical and Chemical Properties (Three Copies):

48597009

- pH; (OPPTS 830.7000).

Volume 11 – Physical and Chemical Properties (Three Copies):

48597010

- Stability to Temperatures, Metals & Metal Ions; (OPPTS 830.6313).

Volume 12 – Physical and Chemical Properties (Three Copies):

48597011

- Oxidation/Reduction; (OPPTS 830.6413).

6314

Volume 13 – Physical and Chemical Properties (Three Copies): 48597012

- UV/Visible Absorption; (OPPTS 830.7050).

Volume 14 – Physical and Chemical Properties (Three Copies): 48597013

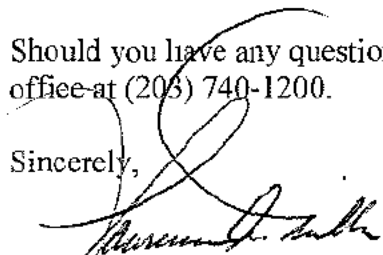
- Vapor Pressure; (OPPTS 830.7950).

We believe that the above items of data are sufficient to support this application for a technical grade active ingredient. Any data requirements deemed as irrelevant to this application are indicated by the appropriate footnotes in the data matrix.

This application for a new pesticide product will fall within the category on Table 4-Registration Division New Products, EPA No. R310; CR No. 46. The PRIA Fee for this application is \$4,807.00.

Should you have any questions or otherwise wish to reach me, please feel free to contact my office at (203) 740-1200.

Sincerely,


Lawrence A. Miller
Principal
Agent for Sinon Corporation



RE: Submission in support of Methomyl Technical (70552-E)

Jane Miller to: Rachel Metz

09/19/2011 10:40 AM

History: This message has been replied to.

1 attachment



Sinon Methomyl Technical_page 13.pdf

Dear Ms. Metz:

Please find attached the corrected page 13 for the Dissociation Constant study.

Best Regards,

Jane M. Miller

115 Obtuse Hill Road
Brookfield, CT 06804

Tel: 203-740-1200
Fax: 203-740-1220

-----Original Message-----

From: Metz.Rachel@epamail.epa.gov [mailto:Metz.Rachel@epamail.epa.gov]
Sent: Thursday, September 15, 2011 9:38 AM
To: jmillar@biologicconsulting.com; lmiller@biologicconsulting.com
Cc: Nair.Sree@epamail.epa.gov
Subject: Re: Submission in support of Methomyl Technical (70552-E)

Dear Mr. Miller,

I am writing to follow up on the conversation your partner and I just had regarding your submission in support of Methomyl Technical (70552-E). There are a few issues with the submission:

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3) One of the guidelines on the checklist for the R310 action code has not been addressed in the submission: boiling point. If this guideline is not applicable to the product, please send something in writing indicating as much.

Thank you for your cooperation in resolving these issues.

Best,
Rachel Metz
Macfadden, EPA Contractor
2777 S. Crystal Drive, S4910B
Arlington, VA 22202
Ph: 703-305-6177
Fax: 703-305-5060



RE: Submission in support of Methomyl Technical (70552-E)
Jane Miller to: Rachel Metz

09/15/2011 10:09 AM

2 attachments



Methomyl Technical Data Matrix_092011.pdf Sinon Certification Form_revised.pdf

Dear Ms. Metz:

Please note the revised Data Matrix and Certification form. I will have Larry look into the Dissociation Constant study.

Best Regards,

Jane M. Miller

115 Obtuse Hill Road
Brookfield, CT 06804

Tel: 203-740-1200
Fax: 203-740-1220

-----Original Message-----

From: Metz.Rachel@epamail.epa.gov [mailto:Metz.Rachel@epamail.epa.gov]
Sent: Thursday, September 15, 2011 9:38 AM
To: jmillers@biologicconsulting.com; lmillers@biologicconsulting.com
Cc: Nair.Sree@epamail.epa.gov
Subject: Re: Submission in support of Methomyl Technical (70552-E)

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Best,
Rachel Metz
Macfadden, EPA Contractor
2777 S. Crystal Drive, S4910B
Arlington, VA 22202
Ph: 703-305-6177
Fax: 703-305-5060



Sinon Methomyl Technical
Lawrence A. Miller

to:

Shyam Mathur

02/15/2012 12:46 PM

Cc:

"sinonusa", "rebecca", "Peter Su"

Hide Details

From: "Lawrence A. Miller" <lmliller@biologicconsulting.com>

To: Shyam Mathur/DC/USEPA/US@EPA

Cc: "sinonusa" <sinonusa@earthlink.net>, "rebecca" <rebecca@sinon.com.tw>, "Peter Su" <PETERSU@sinon.com.tw>

2 Attachments

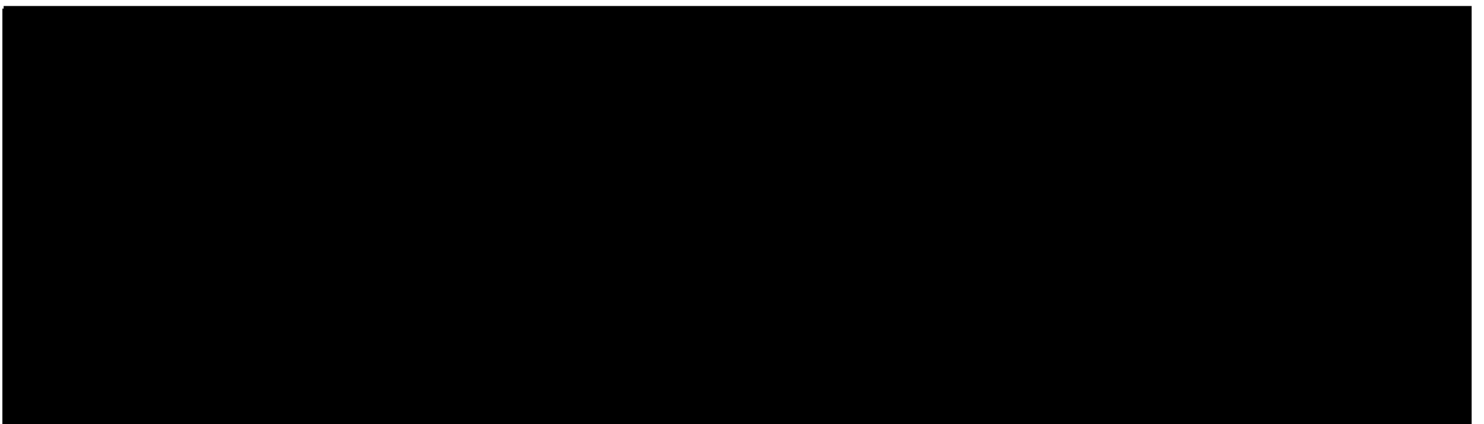


Methomyl Technical CSF - Rev. 2-15-12.pdf



Hi Shyam:

Further to our most recent telephone conversations re: Sinon's Methomyl Technical; EPA file Symbol 70552-E, please note the following responses to your questions:



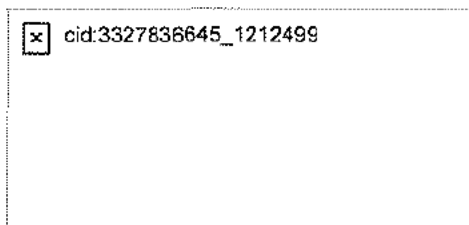
Please give me a call if you need any additional information.

Best Regards,

Larry -

Lawrence A. Miller
BIOLOGIC, Inc.
115 Obtuse Hill Road
Brookfield, CT 06804

Tel: (203) 740-1200
Fax: (203) 740-1220
Email: lmiller@biologicconsulting.com



CONFIDENTIALITY STATEMENT: This electronic message contains information that may be confidential or privileged. The information is intended solely for the use of the individual(s) or entity (ies) named above. If you are not the intended recipient, be aware that any disclosure, copying, distribution, or use of the contents of this message is prohibited. If you have received this email in error, please notify us immediately by telephone at 203-740-1200 or by email reply and delete this message. Thank you.

***** ATTACHMENT NOT DELIVERED *****

This Email message contained an attachment named
image001.jpg
which may be a computer program. This attached computer program could

contain a computer virus which could cause harm to EPA's computers, network, and data. The attachment has been deleted.

This was done to limit the distribution of computer viruses introduced into the EPA network. EPA is deleting all computer program attachments sent from the Internet into the agency via Email.

If the message sender is known and the attachment was legitimate, you should contact the sender and request that they rename the file name extension and resend the Email with the renamed attachment. After receiving the revised Email, containing the renamed attachment, you can rename the file extension to its correct name.

For further information, please contact the EPA Call Center at (866) 411-4EPA (4372). The TDD number is (866) 489-4900.

***** ATTACHMENT NOT DELIVERED *****

21-Day Screen Completed by
Contractor

21-Day Expires on 9-28-11

Jacket # 70552-E

MRID# 485970

Content Screen: Recommend to **Pass/Fail**

86-5 Review: **Pass/Fail/NA**

Overall Status: Recommend to **Pass/Fail**

Transfer This Jacket to:

Stephen Schable

PM

7

Y

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 9-7-11

Experts In-Processing Signature: MF Harrington Date 9-12-11

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>70552-E</u>		EPA Receipt Date: <u>9-7-11</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/oppr001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) <u>Technical + impurities only, no inerts to review</u>			yes	no	
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)			yes	no	
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)			X		
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Initially one of the studies (7-Dissociation Constant) was missing data on page 13 and the 8570-34 form contradicted the data matrix. In addition, boiling point, listed on the R310 checklist, was not addressed in the data matrix or the studies. The registrant was contacted 9/15/11 and sent the last of the corrections 9/19/11.

Several guidelines on the R310 checklist are described on the data matrix as not applicable: flammability, explosability, miscibility, dielectric breakdown voltage, uv/vis, boiling point, and vapor pressure. All tox. studies are listed in one ^{general} line as being cite all.

Technical impurities only - no inerts for review.

Bucket passed.

Studies passed 86-S review.

MRIP A85970

* N/A - Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/opphppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



RE: Submission in support of Methomyl Technical (70552-E)

Jane Miller to: Rachel Metz

09/19/2011 10:40 AM

History: This message has been replied to.

1 attachment



Sinon Methomyl Technical_page 13.pdf

Dear Ms. Metz:

Please find attached the corrected page 13 for the Dissociation Constant study.

Best Regards,

Jane M. Miller

115 Obtuse Hill Road
Brookfield, CT 06804

Tel: 203-740-1200
Fax: 203-740-1220

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From: Metz.Rachel@epamail.epa.gov [mailto:Metz.Rachel@epamail.epa.gov]
Sent: Thursday, September 15, 2011 9:38 AM
To: jmillier@biologicconsulting.com; lmiller@biologicconsulting.com
Cc: Nair.Sree@epamail.epa.gov
Subject: Re: Submission in support of Methomyl Technical (70552-E)

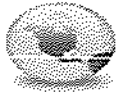
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Macfadden, EPA Contractor
2777 S. Crystal Drive, S4910B
Arlington, VA 22202
Ph: 703-305-6177
Fax: 703-305-5060



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09/15/2011 10:09 AM

2 attachments



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Rachel Metz
Macfadden, EPA Contractor
2777 S. Crystal Drive, S4910B
Arlington, VA 22202
Ph: 703-305-6177
Fax: 703-305-5060



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 12, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-454491
EPA File Symbol or Registration Number: 70552-E
Product Name: METHOMYL TECHNICAL
EPA Receipt Date: 09-Sep-2011
EPA Company Number: 70552
Company Name: SINON CORP

ROBERT G. BUTZ
CARTER LEDYARD & NILBURN LLP
SINON CORP
701 EIGHTH STREET, N.W., SUITE 410
WASHINGTON, DC 20001-3893

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m. J. H.", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{903045Æ~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 7

Receipt No.

S- 903045

EPA File Symbol/Reg. No.

70552-E

Pin-Punch Date:

9/9/2011

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R310

Granted: R310

Amount Due: \$ 4807

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: S. Hill Date: 9/12/11

Remarks:

applicant cites a substantially similar product but does not provide the Active ingredients registration number on the CSF per R300. PM after review of package - if you determine the action needs recording please return to Steve Schaible.

Receipt for Section 3

S: 903045

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 70552 SINON CORP

V

Risk Manager: Registration Division, Risk Management Team 7

Product #: 70552-E Product Name: METHOMYL TECHNICAL

Override#

Me Too
Section3: 352-368

Me Too
Product Name: DUPONT METHOMYL TECHNICAL

Application Date: 30-Aug-2011

OPP Rec'd Date: 09-Sep-2011

Front End Date: 12-Sep-2011

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track ☐

New Ingredient ☐

Receipt Description:

Application for registration of a new product

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:

Jane Miller

From: paygovadmin@mail.doc.twai.gov
ent: Monday, September 05, 2011 1:32 PM
to: jmill@biologicconsulting.com
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 254BNEV6
Agency Tracking ID: 74234706919
Transaction Type: Sale
Transaction Date: Sep 5, 2011 1:31:58 PM

Account Holder Name: Jane M. Miller
Transaction Amount: \$4,807.00
Billing Address: 115 Obtuse Hill Road
City: Brookfield
State/Province: CT
Zip/Postal Code: 06804
Country: USA
Card Type: Visa
Card Number: *****0690

Decision Number:
Registration Number:
Company Name: Simon Corporation
Company Number: 70552
Action Code: R310

September 1, 2011

Mr. John D. Hebert
Product Manager, PM Team 7
Insecticide-Rodenticide Branch
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

SUBJECT: "Methomyl Technical"; EPA File Symbol: 70552-XXX.

Dear Mr. Hebert:

With this letter, we are submitting an application on behalf of Sinon Corporation for the registration of "Methomyl Technical". Please be advised that this application is submitted as a "me-too" registration, and is supported by the cite-all option in accordance with FIFRA 3(c)(1)(D).

In order for the Agency to make its determination of "substantial similarity", and to facilitate the processing of this application, please find the following enclosures:

Volume 1 – Administrative Materials:

- Transmittal Letter
- Application for Pesticide Registration; (EPA Form 8570-1).
- Certification with Respect to Citation of Data (EPA Form 8570-34).
- Data Matrix; (EPA Form 8570-35).
- Confidential Statement of Formula; (EPA Form 8570-4).
- Draft Labeling; (Five Copies).

Volume 2 – Manufacturing Process (Three Copies):

- Product Identity and Composition; (OPPTS 830.1550).
- Description of Materials Used to Produce the Product; (OPPTS 830.1600).
- Description of Production Process; (OPPTS 830.1620).
- Discussion of Formation of Impurities; (OPPTS 830.1670).

Volume 3 – Five-Batch Analysis (Three Copies):

- Preliminary Analysis; (OTPTS 830.1700).
- Certified Limits; (OPPTS 830.1750).
- Enforcement Analytical Method; (OPPTS 830.1800).

Volume 4 – Physical and Chemical Properties (Three Copies):

- Color; (OPPTS 830.6302).
- Physical State; (OPPTS 830.6303).
- Odor; (OPPTS 830.6304)

Volume 5 – Physical and Chemical Properties (Three Copies):

- Melting Point; (OPPTS 830.7200).

Volume 6 – Physical and Chemical Properties (Three Copies):

- Density; (OPPTS 830.7300).

Volume 7 – Physical and Chemical Properties (Three Copies):

- Water Solubility; (OPPTS 830.7840/7860).

Volume 8 – Physical and Chemical Properties (Three Copies):

- Dissociation Constant; (OPPTS 830.7370).

Volume 9 – Physical and Chemical Properties (Three Copies):

- Octanol/Water Partition Coefficient; (OPPTS 830.7550/7570).

Volume 10- Physical and Chemical Properties (Three Copies):

- pH; (OPPTS 830.7000).

Volume 11 – Physical and Chemical Properties (Three Copies):

- Stability to Temperatures, Metals & Metal Ions; (OPPTS 830.6313).

Volume 12 – Physical and Chemical Properties (Three Copies):

- Oxidation/Reduction; (OPPTS 830.6413).

Volume 13 – Physical and Chemical Properties (Three Copies):

- UV/Visible Absorption; (OPPTS 830.7050).

Volume 14 – Physical and Chemical Properties (Three Copies):

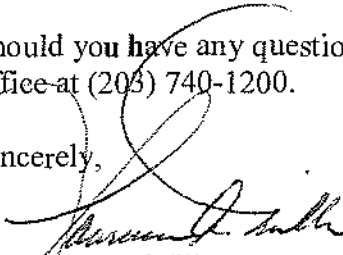
- Vapor Pressure; (OPPTS 830.7950).

We believe that the above items of data are sufficient to support this application for a technical grade active ingredient. Any data requirements deemed as irrelevant to this application are indicated by the appropriate footnotes in the data matrix.

This application for a new pesticide product will fall within the category on Table 4-Registration Division New Products, EPA No. R310; CR No. 46. The PRIA Fee for this application is \$4,807.00.

Should you have any questions or otherwise wish to reach me, please feel free to contact my office at (203) 740-1200.

Sincerely,



Lawrence A. Miller
Principal
Agent for Sinon Corporation



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sinon Corporation c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804	EPA Registration Number/File Symbol 70552-X
Active Ingredient(s) and/or representative test compound(s) Methomyl	Date September 15, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food, Terrestrial Non-Food, Indoor	Product Name Methomyl Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

Sept 15, 2011

Typed or Printed Name and Title

Jane M. Miller, Agent

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGA).
Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or NO (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition					✓	
830.1600	Description of materials used to produce the product					✓	
830.1650	Description of formulation process						✓
830.1670	Discussion on the formation of impurities					✓	
830.1700	Preliminary analysis					✓	
830.1750	Certified limits (158.345)					✓	
830.1800	Enforcement analytical method					✓	

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.6302	Color					✓	
830.6303	Physical State					✓	
830.6304	Odor					✓	
830.6313	Stability to normal and elevated temperatures metal and metal ions					✓	
830.6314	Oxidation/Reduction (Chemical incompatibility)					✓	
830.6315	Flammability						✓
830.6316	Explosibility						✓
830.6317	Storage stability						✓
830.6319	Miscibility						✓
830.6320	Corrosion Characteristics						✓
830.6321	Dielectric Breakdown Voltage						✓
830.7000	pH					✓	
830.7050	UV/ Visible Absorption					✓	
830.7100	Viscosity						✓
830.7200	Melting Point					✓	
830.7220	Boiling Point						✓
830.7300	Density					✓	
830.7370	Dissociation Constant					✓	
830.7550	Partition Coefficient					✓	
830.7840	Water Solubility					✓	
830.7950	Vapor Pressure						✓

Grayed out = data not required

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DATA MATRIX

Date September 15, 2011

EPA Reg. No./File Symbol 70552-XXX

Page 1 of 6

Applicant's/Registrant's Name & Address:

Product:

Sinon Corporation c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804

Methomyl Technical

Ingredient Methomyl

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-1550	Product Identity and Composition		SINON CORPORATION	Own	
830.1600	Description of Materials Used to Produce the Product		SINON CORPORATION	Own	
830.1620	Description of Production Process		SINON CORPORATION	Own	
830-1650	Description of Formulation Process				1
830.1670	Discussion of Formation of Impurities		SINON CORPORATION	Own	
830.1700	Preliminary Analysis		SINON CORPORATION	Own	
830.1750	Certified Limits		SINON CORPORATION	Own	
830.1800	Enforcement Analytical Method		SINON CORPORATION	Own	
830.1900	Submittal of Samples				2
830.6302	Color		SINON CORPORATION	Own	
830.6303	Physical State		SINON CORPORATION	Own	
830.6304	Odor		SINON CORPORATION	Own	
830.6313	Stability to normal & elevated temp., metal, metal ion		SINON CORPORATION	Own	
830.6314	Oxidation/Reduction		SINON CORPORATION	Own	
830.6315	Flammability / Flame Extension				3
830.6316	Exptodability				4

Signature

Name and Title

Date

Jane M. Miller, Agent

09/15/3011

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DATA MATRIX

Date September 15, 2011			EPA Reg. No./File Symbol 70552-XXX		Page 2 of 6
Applicant's/Registrant's Name & Address			Product		
Sinon Corporation c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804			Methomyl Technical		
Ingredient Methomyl					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6317	Storage Stability				5
830.6319	Miscibility				6
830.6320	Corrosion Characteristics				7
830.6321	Dielectric Breakdown Voltage				8
830.7000	pH		SINON CORPORATION	Own	
830.7050	UV/Visible Spectrum		SINON CORPORATION	Own	
830.7100	Viscosity				9
830.7200	Melting Point/ Melting Range		SINON CORPORATION	Own	
820.7220	Boiling Point				9
830.7300	Density		SINON CORPORATION	Own	
830.7370	Dissociation Constant		SINON CORPORATION	Own	
830.7550	Partition Coefficient		SINON CORPORATION	Own	
830.7840	Water Solubility		SINON CORPORATION	Own	
830.7950	Vapor Pressure				10
Signature			Name and Title		Date
<i>Jane M. Miller</i>			Jane M. Miller, Agent		09/15/2011

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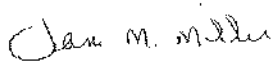
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DATA MATRIX

Date September 15, 2011		EPA Reg. No./File Symbol 70552-XXX		Page 3 of 6	
Applicant's/Registrant's Name & Address		Product:			
Sinon Corporation c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804		Methomyl Technical			
Ingredient Methomyl					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Remaining data requirements including Acute Toxicity, Ecological Effects, Environmental Fate, Residue Chemistry, and all other generic data requirements, including task forces.		CITE-ALL	Farnam Companies, Inc	Pay	
			Phoenix, AZ		
			Bayer Cropscience LP	Pay	
			Research Triangle Park, NC		
			E.I. DuPont De Nemours and Co.	Pay	
			Wilmington, DE		
			Wellmark International	Pay	
			Schaumburg, IL		
			Spray Drift Task Force	Pay	
			Washington, DC		
		Denka International	Pay		
		Westport, CT			
Signature			Name and Title		Date
			Jane M. Miller, Agent		09/15/3011

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DATA MATRIX

Date September 15, 2011			EPA Reg. No./File Symbol 70552-XXX		Page 4 of 6
Applicant's/Registrant's Name & Address			Product		
Sinon Corporation c/o Biologic, Inc. 115 Obluse Hill Road Brookfield, CT 06804			Methomyl Technical		
Ingredient Methomyl					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	CITE-ALL		Burlington Scientific Corporation	Pay	
			Farmingdale, NY		
			Agricultural Reentry Task Force	Pay	
			Washington, DC		
			Troy Corporation	Pay	
			Washington, DC		
			Glades Formulating Corporation	Pay	
			Greeley, CO		
			Agricultural Handlers Exposure TF	Pay	
			Macon, MO		
			Novartis Animal Health US, Inc	Pay	
			Greensboro, NC		
			Rotam Limited	Pay	
			Sarasota, FL		
			Rotam Agrochemical Co. Limited	Pay	
			Sarasota, FL		
Signature			Name and Title		Date
			Jane M. Miller, Agent		09/15/2011

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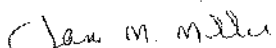
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DATA MATRIX

Date September 15, 2011			EPA Reg. No./File Symbol 70552-XXX		Page 5 of 6
Applicant's/Registrant's Name & Address			Product		
Sinon Corporation c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804			Methomyl Technical		
Ingredient Methomyl					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	CITE-ALL		Residential Exposure Joint Venture	Pay	
			Washington, DC		
			FIFRA Endangered Species T F	Pay	
			Washington, DC		
				Pay	
				Pay	
				Pay	
				Pay	
				Pay	
				Pay	
Signature			Name and Title		Date
			Jane M. Miller, Agent		09/15/2011

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DATA MATRIX FOOTNOTES

1. **Description of Formulation Process:** Not applicable because the product is a TGA/MP.
2. **Submittal of Samples:** Not required at this time.
3. **Flammability / Flame Extension:** Not applicable. Product does not contain combustible liquids.
4. **Explosibility:** Not applicable. Product is not potentially explosive.
5. **Study in progress.**
6. **Miscibility:** Not applicable. Product is not intended for dilution with petroleum solvents.
7. **Study in progress**
8. **Dielectric Breakdown Voltage:** Not applicable. Product is not intended for use around electrical equipment.
9. **Viscosity/Boiling Point:** Not required because product is a solid.
10. **Vapor Pressure:** Not required since Methomyl is a solid at ambient temperatures and would therefore have negligible vapor pressure under normal storage conditions.

FOR OFFICIAL USE ONLY

FILE SYMBOL

REGISTRATION NO.

70552-E

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
SEP - 9 2011		

Do Not Write Comments,
Formula, or Parts of Formula
on This Envelope

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

82-83 Confidential Statement of Formula may be entitled to confidential treatment